CLAIMS:

1. A method of suppressing rejection of an organ or tissue transplant in an animal comprising the following steps:

(a) administering to the animal an antibody directed at a cell surface antigen selected from the group consisting of CD4, CD8, CD154, LFA-1, CD80, CD86 and ICAM-1, and a non-cellular protein antigen to generate a population of regulatory T-lymphocytes;

(b) reactivating said population of regulatory T-lymphocytes by further administration to the animal of the non-cellular protein antigen; and

(c) transplanting said organ or tissue whilst said population of regulatory T-lymphocytes is activated.

2. A method of treating a condition in an animal mediated by an immune response which comprises administering to said animal an antibody directed at a cell surface antigen selected from the group consisting of CD4, CD8, CD154, LFA-1, CD80, CD86 and ICAM-1, and a non-cellular protein antigen to generate a population of regulatory T-lymphocytes which are then re-activated by subsequent administration of the original non-cellular antigen.

3. The method of claim 2, wherein the condition is an autoimmune condition.

4. The method of claim 2 or 3, wherein the autoimmune condition is selected from the group consisting of rheumatoid arthritis, multiple sclerosis, insulin dependent diabetes mellitus and inflammatory bowel disease.

5. The method of any preceding claim wherein the animal is also treated with an immunosuppressive agent or other adjunctive therapy.

6. The method of claim 5 wherein the animal is treated with a sub-therapeutic dose of an immunosuppressive agent.

7. The method of claim 5 wherein the other adjunctive therapy comprises treatment with an anti-CD8 antibody.

8. The method of any preceding claim, wherein the animal is a human.

9. The method of any preceding claim, wherein the antibody is an anti-CD4 antibody.

10. The method of claim 9, wherein the antibody is a non-depleting anti-CD4 antibody.

11. The method of any preceding claim, wherein the antibody is a chimeric or humanised antibody.

12. The method of any preceding claim, wherein the antibody is administered parenterally.

13. The method of any preceding claim, wherein the antibody is administered intravenously.

14. The method of any preceding claim, wherein the antibody is formulated or administered together with at least one physiologically acceptable carrier.

15. The method of claim 14, wherein the physiologically acceptable carrier is sterile isotonic buffered saline.

16. The method of any preceding claim, wherein the non-cellular protein antigen is administered parenterally.

17. The method of any preceding claim, wherein the antibody is administered to the animal in a dose in the range 0.25 to 25mg/kg.

18. The method of any preceding claim, wherein the antibody is administered to the animal in a dose in the range 5 to 10mg/kg.

19. The method of claim 17 or 18, wherein 1 to 5 such doses are administered to the animal.

20. The method of claim 17 or 18, wherein 2 or 3 such doses are administered to the animal.

21. The method of any preceding claim, wherein the non-cellular protein antigen is selected from the group consisting of human gamma globulin, equine gamma globulin and ovalbumin.

22. Use of an antibody directed at a cell surface antigen selected from the group consisting of CD4, CD8, CD154, LFA-1, CD80, CD86 and ICAM-1, for the manufacture of a medicament for the suppression of rejection of an organ or tissue transplant in an animal by a method which comprises administering the antibody to the animal together with a non-cellular protein antigen to generate in the animal a population of regulatory T-lymphocytes; reactivating said population of regulatory T-lymphocytes by further administration to the animal of the non-cellular protein antigen; and transplanting said organ or tissue whilst said population of regulatory T-lymphocytes is activated.

23. Use of a non-cellular protein antigen for the manufacture of a medicament for the suppression of rejection of an organ or tissue transplant in an animal by a method which comprises administering an antibody directed at a cell surface antigen selected from the group consisting of CD4, CD8, CD154, LFA-1, CD80, CD86 and ICAM-1, to the animal together with the non-cellular protein antigen to generate in the animal a population of regulatory T-lymphocytes; reactivating said population of regulatory T-lymphocytes by further administration to the animal of the non-cellular protein antigen; and transplanting said organ or tissue whilst said population of regulatory T-lymphocytes is activated.

24. Use of an antibody directed at a cell surface antigen selected from the group consisting of CD4, CD8, CD154, LFA-1, CD80, CD86 and ICAM-1, for the manufacture of a medicament for the treatment of a condition in an animal mediated by an immune response by a method which comprises administering the antibody to the animal together with a non-cellular protein antigen to generate in the animal a population of regulatory T-lymphocytes which are then re-activated by subsequent administration of the original non-cellular antigen.

25. Use of a non-cellular protein antigen for the manufacture of a medicament for the treatment of a condition in an animal mediated by an immune response by a method which comprises administering the non-cellular protein antigen to the animal together with an antibody directed at a cell surface antigen selected from the group consisting of CD4, CD8, CD154, LFA-1, CD80, CD86 and ICAM-1, to generate in the animal a population of regulatory T-lymphocytes which are then re-activated by subsequent administration of the original non-cellular antigen.

26. The use of claim 24 or 25, wherein the condition is an autoimmune condition.

27. The use of one or more of claims 24 to 26, wherein the autoimmune condition is selected from the group consisting of rheumatoid arthritis, multiple sclerosis, insulin dependent diabetes mellitus and inflammatory bowel disease.

28. The use of one or more of claims 22 to 27 wherein the animal is also treated with an immunosuppressive agent or other adjunctive therapy.

29. The use of claim 28 wherein the animal is treated with a sub-therapeutic dose of an immunosuppressive agent.

30. The use of claim 28 wherein the animal is also treated with an anti-CD8 antibody.

31. The use of one or more of claims 22 to 30, wherein the animal is a human.

32. The use of one or more of claims 22 to 31, wherein the antibody is an anti-CD4 antibody.

33. The use of claim 32, wherein the antibody is a non-depleting anti-CD4 antibody.

34. The use of one or more of claims 22 to 33, wherein the antibody is a chimeric or humanised antibody.

35. The use of one or more of claims 22 to 34, wherein the antibody is administered parenterally.

36. The use of one or more of claims 22 to 34, wherein the antibody is administered intravenously.

37. The use of one or more of claims 22 to 36, wherein the antibody is formulated or administered together with at least one physiologically acceptable carrier.

38. The use of claim 37, wherein the physiologically acceptable carrier is sterile isotonic buffered saline.

39. The use of one or more of claims 22 to 38, wherein the non-cellular protein antigen is administered parenterally.

40. The use of one or more of claims 22 to 39, wherein the antibody is administered to the animal in a dose in the range 0.25 to 25mg/kg.

41. The use of one or more of claims 22 to 40, wherein the antibody is administered to the animal in a dose in the range 5 to 10mg/kg.

42. The use of claim 40 or 41, wherein 1 to 5 such doses are administered to the animal.

43. The use of claim 40 or 41, wherein 2 or 3 such doses are administered to the animal.

44. The use of one or more of claims 22 to 43, wherein the non-cellular protein antigen is selected from the group consisting of human gamma globulin, equine gamma globulin and ovalbumin.

45. An *ex vivo* method for generating a population of regulatory T lymphocytes comprising culturing T cells with an antibody directed at a cell surface antigen selected from the group consisting of CD4, CD8, CD154, LFA-1, CD80, CD86 and ICAM-1, in the presence of cells that present either alloantigen or a non-cellular protein antigen.

46. The method of claim 45, wherein the non-cellular protein antigen is selected from the group consisting of human gamma globulin, equine gamma globulin and ovalbumin.

47. The method of claim 45, wherein the T cells are taken from a recipient animal and the cells that present alloantigen are either cells taken from a donor animal or cells pulsed with antigen taken from a donor animal.

48. A method of suppressing rejection of an organ or tissue transplant in a recipient animal comprising the following steps:

(e) taking a sample of T cells from the recipient animal;

(f) taking a sample of alloantigen from a donor animal, said donor animal being the source of the organ or tissue being transplanted;

(g) exposing said sample of T cells to said sample of alloantigen in the presence of an antibody directed at a cell surface antigen selected from the group consisting of CD4, CD8, CD154, LFA-1, CD80, CD86 and ICAM-1 to generate a population of regulatory T lymphocytes;

(h) administering to the recipient animal said population of regulatory T-lymphocytes.

49. The method of claim 48 wherein said population of regulatory T-lymphocytes is administered to the recipient animal after transplant of an organ or tissue.

50. The method of one or more of claims 47 to 49, wherein the animal is a human.

51. The method of one or more of claims 45 to 50, wherein the antibody is an anti-CD4 antibody.

52. The method of claim 51, wherein the antibody is a non-depleting anti-CD4 antibody.

53. The method of one or more of claims 45 to 52, wherein the antibody is a chimeric or humanised antibody.

54. Regulatory T lymphocytes produced by the method of one or more of claims 45 to 47 for use in therapy.

55. Use of regulatory T lymphocytes produced by the method of one or more of claims 45 to 47 for the manufacture of a medicament for the suppression of rejection of an organ or tissue transplant in an animal.

56. The method of any of claims 1 to 21 further comprising the following step:

administering to the animal a population of regulatory T-lymphocytes produced according to the method of one or more of claims 45 to 47.

57. The method of claim 56 for suppressing rejection of an organ or tissue transplanted in an animal, wherein said population of regulatory T lymphocytes is produced according to the method of claim 47 and said donor animal is the source of the organ or tissue that was transplanted in step (c).

58. The use of any of claims 22 to 45, wherein the method further comprises administering to the animal a population of regulatory T-lymphocytes produced according to the method of one or more of claims 45 to 47.

59. The use of claim 58, wherein the method is for suppressing rejection of an organ or tissue transplanted in an animal, the method further comprises administering to the animal a population of regulatory T lymphocytes produced according to the method of claim 47 and said donor animal is the source of the organ or tissue that was transplanted.